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10/083,727	02/27/2002	Radislav Alexandrovich Potyrailo	RD-28,645	6196

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General Electric Company
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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,727	POTYRAILO ET AL	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 18-31, 41-54 and 59-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 32-40 and 55-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>02/02</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of species A, C, E (Claims 1-17, 32-40, 55-58) in papers filed 6 October 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)) and is therefore made FINAL.

Claim Objections

2. Claim 14 objected to because of the following informalities: The comma between "dipping and draining" is missing.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-17, 32-40, 55-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-17, 32-40, 55-58 are indefinite in Claim 1 because the claim is drawn to a method of generation and screening three dimensional array, but the claim does not recited method steps of screening. Therefore, it is unclear whether the method steps perform the claimed method.

b. Claims 1-17, 32-40, 55-58 are indefinite in Claim 1 for the recitation “(x, y, and z)” because it is unclear whether a recitation within parenthesis adds limitations to the claims.

c. Claims 1-17, 32-40, 55-58 are indefinite in Claim 1, lines 7 & 8 for the recitation “the sample array” because the recitation lacks proper antecedent basis in the “array of samples” recited in line 6. It is suggested that Claim 1 be amended to provide proper antecedent basis.

d. Claim 2 is indefinite for the recitation “the array comprises multiple two dimensional arrays” because it is unclear what limitations are being added to the method steps of Claim 1. The recitation is further indefinite because Claim 1, line 6 recites “to generate a three dimensional array”. As such it is unclear whether the limitations of Claim 2 the three-dimensional array of Claim 1 or to additional arrays not described in Claim 1.

e. Claims 3 and 5-17 are indefinite in Claim 3 for the recitation “comprises samples deposited on the surface” because it is unclear whether the recitation describes the array or whether the recitation is intended to be a method step of depositing on the surface.

f. Claims 3 and 5-17 are indefinite in Claim 3 further indefinite for the recitation “the surface” because the recitation lacks proper antecedent basis in Claim 1.

g. Claim 4 is indefinite for the recitation “the use of masking and gradient deposition” because it is unclear whether the recitation is intended as a method step of masking and gradient deposition. It is suggested that the claim be amended to recite positive and active method steps e.g. “wherein said depositing comprises masking and gradient deposition”.

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h. Claims 5-7 are indefinite in Claim 5 for the recitation “further comprising evaporative methods for depositing” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the depositing step of Claim 1.

i. Claim 7 is indefinite for the recitation “further comprising molecular beam epitaxy” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the evaporative method of Claim 5.

j. Claims 8 and 9 are indefinite in Claim 8 for the recitation “further comprising glow-discharge processes for deposition” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the depositing step of Claim 1.

k. Claim 9 is indefinite for the recitation “further comprising chemical vapor deposition” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the depositing step of Claim 1.

l. Claim 12 is indefinite for the recitation “further comprising pulsed-laser deposition for deposition” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the depositing step of Claim 1.

m. Claims 13 and 14 are indefinite in Claim 13 for the recitation “further comprising mechanical deposition” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the deposition of Claim 1.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5-6, 13-17, 32-37, 39-40, 55-58 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Walt et al (U.S. Patent No. 6,327,410, issued 4 December 2001).

Regarding Claim 1, Walt et al disclose a method for generation and screening of three dimensional arrays comprising, depositing a plurality of samples onto at least one substrate at discrete and defined positions in a three dimensional format such that each sample is isolated from other samples (i.e. attached to a microsphere), collecting data from the sample array, correlating data to the position of the sample and analyzing the data (Column 3, lines 30-45 and Column 22, lines 8-26) and wherein each sample is defined by x, y, z coordinates i.e. x and y being the axis of the substrate (Column 6, lines 4-21) and z being the size/diameter of the microsphere (Column 19, lines 6-12) and/or presence or absence of bead (Column 18, lines 35-40).

Regarding Claim 2, Walt et al disclose the method wherein the array comprises multiple two-dimensional arrays i.e. sub-arrays within the array (Column 18, line 59-Column 19, line 5).

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Regarding Claim 3, Walt et al disclose the method wherein the array comprises samples on the surface of a three-dimensional structure i.e. microsphere (Column 11, lines 41-67).

Regarding Claim 5, Walt et al disclose the method wherein evaporative methods for deposition is used i.e. the microsphere solution is evaporated (Column 17, lines 46-59).

Regarding Claim 6, Walt et al disclose the method wherein the evaporative methods utilized filaments i.e. optical fibers (Column 17, lines 11-59).

Regarding Claim 13, Walt et al disclose the method comprising mechanical deposition (Column 17, lines 46-59).

Regarding Claim 14, Walt et al disclose the method mechanical deposition comprises flow coating i.e. dripping (Column 17, lines 46-59).

Regarding Claims 15-17, Walt et al disclose the method wherein the samples have a thickness ranging from 10nm to 200µm i.e. microsphere diameter range (Column 7, lines 32-40).

Regarding Claim 32, Walt et al disclose the method further comprising treating the deposited samples to initiate a chemical reaction within the array i.e. contacting the array with bioagent-specific analytes (Column 19, line 54-Column 21, line 60).

Regarding Claim 33, Walt et al disclose the method wherein the treatment comprises addition of a chemical agent e.g. Ca^{2+} , Mg^{2+} (Column 20, Table III).

Regarding Claim 34, Walt et al disclose the method wherein treatment is applied differentially to at least some of the locations of the array i.e. selected sites are photoactivated for microsphere attachment (Column 18, lines 41-47).

Regarding Claim 35, Walt et al disclose the method wherein the treatment is applied in a constant manner to all locations of the array (Example 1, Column 26, lines 50-65).

Regarding Claim 36, Walt et al disclose the method wherein treatment comprises application of electromagnetic radiation i.e. light (Column 15, line 64-Column 16, line 20).

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Walt et al teach the method wherein following addition of bioagent-specific analytes the microspheres are treated (exposed to) light. The open claim language “comprises” encompasses the treatment steps of Walt et al.

Furthermore, Walt et al disclose the method wherein light is applied to the microspheres to chemically link the microspheres to the fiber optic substrate (Column 18, lines 41-47).

Regarding Claim 37, Walt et al disclose the method wherein the treatment comprises the application of ultrasound i.e. sonication (Column 17, lines 31-52 and Column 18, lines 33-35).

Regarding Claim 39, Walt et al disclose the method wherein the substrate is substantially inert i.e. optical fiber substrate comprising microspheres (Column 5, lines 49-60).

Regarding Claim 40, Walt et al disclose the method wherein the substrate comprises a substance that interacts with at least some of the samples of the array i.e. the optical fibers comprises photoactivatable linkers for chemical attachment of the microspheres (Column 18, lines 41-47) and the microspheres comprise functional groups for sample (bioactive agent) interaction (Column 11, line 63-Column 12, line 25). Therefore both, the optical fiber substrate and microsphere substrate meet the limitations of the claim.

Regarding Claim 55, Walt et al disclose the method wherein collecting analytical data from the array is substantially simultaneous for each sample of the array (Example 1, Column 26, lines 36-60).

Regarding Claim 56, Walt et al disclose the method wherein collecting analytical data from the array is performed separately for each sample i.e. individual microspheres (Column 16, lines 59-63).

Regarding Claim 57, Walt et al disclose the method wherein the analysis comprises univariate analysis (Column 16, lines 59-63).

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Regarding Claim 58, Walt et al disclose the method wherein the analysis comprises multivariate analysis (Example 1, Column 26, lines 25-60).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4, 7-12 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,327,410, issued 4 December 2001) in view of Chen et al (U.S. Patent No. 6,638,760, filed 3 December 1998).

Regarding Claims 4 and 7-12, Walt et al teach the method for generation and screening of three dimensional arrays comprising, depositing a plurality of samples onto at least one substrate at discrete and defined positions in a three dimensional format such that each sample is isolated from other samples (i.e. attached to a microsphere), collecting data from the sample array, correlating data to the position of the sample and analyzing the data (Column 3, lines 30-45 and Column 22, lines 8-26) and wherein each sample is defined by x, y, z coordinates i.e. x and y being the axis of the substrate (Column 6, lines 4-21) and z being the size/diameter of the microsphere (Column 19, lines 6-12).

Walt et al further teach that the method further comprises masking (Column 18, lines 41-47) and any of a variety of deposition techniques known in the art (Column 11, line 63-

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Column 12, line 64) which suggests that any deposition technique would function equally well in their method. But they do not specifically teach gradient deposition, molecular beam epitaxy, glow-discharge deposition, chemical vapor deposition or pulsed-laser assisted deposition.

However, Chen et al teach a similar method for generation and screening of three dimensional arrays and they also teach that variety of deposition techniques known in the art are useful for creating the desired arrays having appropriate density e.g. chemical vapor deposition (Column 10, lines 21-47).

Therefore, because Walt et al and Chen et al teach that any deposition techniques known in the art would function equally and because the claimed deposition techniques were known in the art, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply gradient deposition, glow-discharge deposition, chemical vapor deposition or pulsed-laser assisted deposition to the deposition of Walt et al based on available equipment and desired results.

Regarding Claim 38, Walt et al teach the method further comprising treating deposited samples to initiate a chemical reaction e.g. hybridization (Column 19, line 54-Column 21, line 60, especially Column 21, lines 17-60) but they are silent regarding the treatment comprising a change in temperature. However, Chen et al teach the similar method comprising treating samples to initiate hybridization comprising changing the temperature i.e. heating to 37° C to hybridize and further heating to 98° C to denature (Column 22, lines 13-62). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the temperature change of Chen et al to the hybridization of Walt et al for the obvious benefits of sequencing specifically captured molecules as taught by Chen et al (Column 22, lines 13-62).

Prior Art

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. Labaer et al (U.S. Patent Application Publication No. 2002/0192673, filed 22 January 2002 with priority to 23 January 2001) teach three-dimensional substrates (§ 330-334).

b. Campbell et al (U.S. Patent No. 6,168,914, issued 2 January 2001) teach three-dimensional substrate (Fig. 1-5).

c. Patek et al (U.S. Patent No. 6,541,211, filed 24 November 1999) teach three-dimensional substrates (Fig. 5 and Column 10, lines 51-67).

d. Baum (U.S. Patent Application Publication No. 2003/0068644, filed 20 May 1998) teaches three-dimensional substrates (Fig. 13, 25-29).

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 19, 2003